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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,263	01/26/2001	Gale Arthur Granger	IRVN-005CIP	7988

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EXAMINER
YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
1642	12

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/771,263	THOMPSON ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-26* is/are pending in the application.

4a) Of the above claim(s) *16-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-15,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendment filed 3/17/2003 (paper no. 11) is acknowledged and entered into the record. Accordingly, claim 1 is canceled without prejudice or disclaimer. Claims 2-26 are pending, claims 16-24 are withdrawn from further consideration as being drawn to non-elected inventions. Applicant is reminded to cancel all drawn to non-elected inventions.

2. Therefore, claims 2-15 and 25-26 are examined on the record.

Specification

3. The specification is objected to because of the following informalities: there are numerous typographical errors through out the specification, including spelling grammatical and erroneous punctuation, for example on pages 10,11,15,16,19,20, 34, 48, etc. Applicant has indicated that corrections to the specification will be made upon notice of allowance. Applicant has also requested that the examiner specifically point out where in the specification such errors exist (see for example, on page 10, line 19 the term "afoandgens"). The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections Withdrawn - 35 USC § 103

4. The rejection of claims 2,5,9,11,13,14,25, and 26 under 35 USC 103(a) as being obvious over US patent 6,203,787 is withdrawn in view of the arguments set forth by the applicant.

Claim Rejections Withdrawn - 35 USC § 102

5. The rejection claim 26 under 35 USC 102(b) as being anticipated by Kohler *et al* is withdrawn.

Double Patenting- Maintained

6. The rejection of claims 2,5,9,11,13,14,25, and 26 under the judicially created doctrine of obviousness type double patenting is maintained for the reasons of record. Applicant has stated an intent to file a terminal disclaimer upon indication of allowable subject matter. Because a terminal disclaimer has not been filed, this rejection is maintained.

Claim Rejections Maintained - 35 USC § 102

7. The rejection of claims 2-5, 9 and now claims 25,8, and 10-12 under 35 USC 102(b) as being obvious over Kohler PC *et al* is maintained for the reasons of record. Applicant argues that the composition of Kohler PC *et al* differs from the instant invention in that the instant composition is formulated for administration into a solid tumor or tumor bed. Applicant's arguments have been carefully considered but are not found persuasive. The composition of the instant invention comprises alloactivated lymphocytes. The composition of Kohler PC *et al* also comprises alloactivated lymphocytes. Because the product of the prior art is, in the absence of evidence to the contrary, identical to that disclosed by the instant invention and because the intended usage of the product does not carry any patentable weight, the prior art reads of the claims of the instant invention as currently, interpreted. Regardless of how the applicant intends to use the product, the product disclosed in the prior art is the same.

Furthermore, in the absence of evidence to the contrary, the culture of the lymphocytes for 6-12 days in culture would exhibit the highest levels of IFN-γ and IL-2.

Claim Rejections Maintained - 35 USC § 102

8. The rejection of claims 2,8,13 and now claims 25, 9-12 under 35 USC 102(b) as being anticipated by Philips *et al* is maintained for the reasons of record. Applicant agues that the invention of the instant invention is not intended to "make killer cells directly out of the patient's own cell in culture," and further argues that the inclusion of pharmaceutical excipients are not recited. Applicant's arguments have been carefully considered but are not found persuasive. The product claimed is identical to that already taught in the prior art reference. Regardless of what the intended usages maybe, a product is still a product regardless of how the product is made or its intended usage. With regards to the pharmaceutical excipients, the main component of the product is identical and the addition of excipients would be considered a design choice and does not render the product claimed patentable distinguishable over the prior art. Newly rejected claims 25 is anticipated because original claim 1 has now been canceled and the limitations of claim 1 have been incorporated into claim 25. Claims 9-12 are rejected because the process of making the product regardless of the method is not deem a patentable distinction when it applies to products.

Claim Rejections Maintained - 35 USC § 103

9. The rejection of claim 13 under 35 USC 103(a) as being obvious over Kohler PC *et al* in view of Philips *et al* is maintained for the reasons of record. Applicant argues that there is no motivation to combine the references and further argues for the same

reasons set forth for the 35 USC 102 rejections made, the references do not combine to obviate the instant rejection. Applicant's arguments have been carefully considered but are not found persuasive. For the same reasons already made in the rejections made, *supra*, the product claimed in the prior art is identical to that instantly claimed. The limitation of culturing the cells for specific time points is an obvious modification because Philips *et al* teaches such a method of culturing his alloactivated lymphocytes. Because this limitation is considered a design choice, it would have been obvious to one of ordinary skill to use the culturing times set forth by Philips *et al* to modify the culturing procedures of Kohler *et al*.

NEW ARGUMENTS

Double Patenting

10. Claims 6,7,and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1-6, 8-9, and 19-20 of U.S. Patent No. 6207147. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the US Patent 6207147 is identical to the scope of the instantly claimed invention. The claims of the instant invention are drawn to a composition that comprises alloactivated lymphocytes and a tumor associated antigen (TAA), wherein the TAA is expressed on a tumor cell present in the composition. The claims are further limited to a kit comprising the said composition. US Patent 6207147 is drawn to a composition comprising leukocytes that are activated by allogeneic lymphocytes and TAA. The claims of the US Patent 6207147 are also drawn to a kit comprising the said lymphocytes. The products

claimed in the instant application and those already claimed in the US Patent 6207147 fall within the same scope.

Conclusion

No claims are allowed. Claim 14 is objected to because it depends from a claims that is rejected. This action is made NON-FINAL to allow the applicant a chance to respond to the newly cited rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
May 21, 2003

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600